State of South Dakota

SEVENTY-SIXTH SESSION
LEGISLATIVE ASSEMBLY, 2001

175E0028

SENATE BILL NO. 1

Introduced by: Senators Madden and Ham and Representatives McCoy and Slaughter at the request of the Interim Judiciary Committee

FOR AN ACT ENTITLED, An Act to require written informed consent before genetic testing.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF SOUTH DAKOTA:

Section 1. Terms used in this Act mean:

(1) "Genetic information," information derived from a genetic test about a gene, gene product, or inherited characteristic;

(2) "Genetic test," the analysis of human DNA, RNA, chromosomes, and those proteins and metabolites used to detect heritable or somatic disease-related genotypes or karyotypes for the purpose of determining the presence or absence of genes that exhibit abnormalities, defects, or deficiencies, including carrier status, that are known to be the cause of a disease or disorder, or are determined to be associated with a statistically increased risk of development of a disease or disorder. The term, genetic test, does not include a routine physical examination or a routine analysis, including, a chemical analysis, of body fluids, unless conducted specifically to determine the presence, absence, or mutation of a gene or chromosome, and the term, genetic test, does not include a procedure performed as a component of biomedical research that

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is conducted pursuant to federal common rule under 21 C.F.R. parts 50 and 56 and 45 C.F.R. part 46;

(3) "Predictive genetic test," a genetic test performed for the purpose of predicting the future probability that the person tested will develop a genetically related disease or disability;

(4) "Presymptomatic genetic test," a genetic test performed before the onset of clinical symptoms or indications of disease.

Section 2. No person may order a presymptomatic or predictive genetic test without first obtaining the written, informed consent of the person to be tested. For purposes of this section, written, informed consent consists of a signed writing executed by the person to be tested or the legally authorized representative of the person to be tested that includes, at a minimum, all of the following:

(1) The nature and purpose of the presymptomatic or predictive genetic test;

(2) The effectiveness and limitations of the presymptomatic or predictive genetic test;

(3) The implications of taking the presymptomatic or predictive genetic test, including, the medical risks and benefits;

(4) The future uses of the sample taken from the person tested in order to conduct the presymptomatic or predictive genetic test and the information obtained from the presymptomatic or predictive genetic test;

(5) The meaning of the presymptomatic or predictive genetic test results and the procedure for providing notice of the results to the person tested; and

(6) Who will have access to the sample taken from the person tested in order to conduct the presymptomatic or predictive genetic test and the information obtained from the presymptomatic or predictive genetic test, and the person's right to confidential

treatment of the sample and the information.

Section 3. If a person to be tested or the person's legally authorized representative signs a copy of the informed consent form developed pursuant to section 2 of this Act, the person obtaining the informed consent shall give the person to be tested a copy of the signed informed consent form and shall include the original signed informed consent form in the medical record of the person tested.